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TITLE: Increasing Adherence to Follow-up of Breast Abnormalities in Low-Income Korean American Women: A Randomized Controlled Trial

PRINCIPAL INVESTIGATOR: Annette Maxwell, Ph.D.

CONTRACTING ORGANIZATION: University of California
Los Angeles, CA 90095-6900

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Annette Maxwell, Ph.D.

E-Mail: amaxwell@ucla.edu

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14. ABSTRACT
Purpose and Scope: The purpose of this study is to design and test an intervention to assist Korean American women who have been identified with a potential breast abnormality through the Breast Cancer Early Detection Program (BCEDP) and who have missed their first follow-up appointment (at-risk women). The intervention takes place in the form of peer navigation which includes reminder phone calls or home visits by a trained peer counselor to explain the importance of follow-up procedures, emotional support, help with transportation to follow-up appointments, translations, organizing care for children or grandchildren during medical appointments, and other assistance to overcome barriers to follow-up identified during the initial phase of the study. Major Findings: A total of 137 eligible Korean American women have consented to participate in the study. Preliminary analyses of the follow-up surveys suggest that our intervention is effective in increasing adherence to follow-up of breast abnormalities in low-income Korean American who are screened through BCEDP. Complete follow-up is reported by 68% of the women in the control group and 93% of the women in the intervention group. This difference is statistically significant (Fisher's exact test, $p<.0007$). We will have to assess if chart reviews confirm these self-report findings.

15. SUBJECT TERMS
Adherence to follow-up of breast abnormalities; low-income Korean Women; randomized controlled trial; peer counseling intervention

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INTRODUCTION:

The purpose of this study is to design and test an intervention to assist Korean American women who have been identified with a potential breast abnormality through the Breast Cancer Early Detection Program (BCEDP) and who have missed their first follow-up appointment (at-risk women). The intervention takes place in the form of peer navigation which includes reminder phone calls or home visits by a trained peer counselor to explain the importance of follow-up procedures, emotional support, help with transportation to follow-up appointments, translations, organizing care for children or grandchildren during medical appointments, and other assistance to overcome barriers to follow-up identified during the initial phase of the study.

As reported previously, phase I of the study informed us that a peer navigator intervention may greatly facilitate adherence to follow-up of breast abnormalities by Korean American at-risk women. We have therefore designed an intervention that utilizes a peer navigator model. We are currently conducting a randomized controlled trial to assess the effectiveness of our intervention. We have recruited 137 subjects into our protocol. We have also collected extensive process measures including number and type of intervention activities requested and delivered in order to estimate the feasibility for institutionalizing intervention activities.

BODY:

Following activities as listed in the Statement of Work have been completed:

Task 1: Setup and Formative Research

All of the task 1 components have been completed and have been addressed in our previous reports.

Task 2: Enrolling Subjects into Randomized Trial

a. Identify eligible subjects (N=253 during the 2 year recruitment), randomize into the study and administer verbal informed consent to intervention subjects (choice of English or Korean).

Since August 2005, based on the BCEDP clinic logs at the two clinics, we have identified 178 eligible subjects. This number does not include 15 women who became eligible 6 months prior to the beginning of the prospective study, which were previously included in our counts. We allocated 93 women to the prospective intervention arm and 85 women to the retrospective usual care control arm of the study. We obtained consent to participate from 79/93 women in the prospective intervention arm (85%) and from 58/85 women in the retrospective usual care control arm (68%).

Task 3: Conducting Intervention

a. Conduct telephone needs assessment and counseling for each newly enrolled intervention subject (N=86). Contact each intervention subject at least once every other week until completion of diagnostic follow-up/treatment. Offer intervention components as appropriate.

Each woman in the intervention arm has been contacted through telephone or in-person by our peer navigator for needs assessment using our Initial Assessment and Intervention Survey Questionnaire. Once the initial assessment has been made, our peer navigator follows up with each patient to address their identified need (i.e. reminder call prior to appointment, provide transportation, provide translation, fill out paper work at the hospital, provide emotional support, answer questions, etc.). A total of 79 women have undergone Initial Assessment and have received the peer navigator intervention.

b. Document all contacts, responses to needs assessment questions, intervention requests and activities.

We are successful in contacting the majority of our subjects through telephone. Initial contacts are made through telephone using the numbers given to us by the participating clinics. Clinics give us one or more telephone numbers and an address for each woman. If we are not successful with the telephone numbers (i.e. disconnected or no longer residing at such location), we contact the clinic for accuracy of numbers and obtain any other alternate numbers. In order to keep track of how much time and how much effort are given to each woman, we are logging all of these activities.

Thus far, 79 women have received assistance from the peer navigator. They have received help in the following ways:

- Reminder calls (64)
- Providing with transportation (3)
- Rescheduling appointments (42)
- In-person help at the hospital (49)
    - Help with translation (50)
    - Help with filling out the forms (49)
- Providing reassurance (52)
- Answering questions (62)
- Providing directions to the hospital (22)

c. Conduct alternative protocol for intervention subjects who cannot be reached by telephone.

We mailed a questionnaire to women that we were not able to reach by phone. However, none of the women responded to the mailed questionnaire.

d. After completion of the follow-up survey, provide intervention to women in the control group who did not complete follow-up procedures.

Many of the women in the control condition eventually complete their follow-up of abnormalities. We are keeping track of how long it took for them to complete their follow-up to assess whether our intervention could shorten this length of time. For those that did not complete their follow-up, we will offer the identical intervention after we complete the 6 month follow-up survey questionnaire. Of the 58 women in the control arm who have completed the survey to date, 39 have completed their follow-up of abnormalities based on self-report. We offered help to the 19 women in the control arm who did not complete follow-up. Only two women agreed to receive help and completed their follow-up with the help of the peer navigator.

Task 4: Collecting Data

a. Collect and compile log sheets from contacts with intervention subjects (process measures) into a data base
Information from the log sheets is being entered into a data base. This task is ongoing.

Components b-c have been completed and have been addressed in our previous report.

d. Conduct post-intervention survey with all subjects (N=160) 6 months after referral for diagnostic follow-up. Administer verbal consent prior to conducting survey to subjects in the control group.
We have completed 117 interviews (58 control, 59 intervention).

e. Conduct chart reviews for all subjects 6 months after referral for diagnostic follow-up.

We will not be able to conduct chart reviews for all subjects since most women in the control arm did not give consent to this activity. Only 12 women in the control arm have signed the HIPAA forms while a total of 50 women in the intervention arm have signed the forms. This may be due to the fact that we don't have face to face contact with women in the control arm. We have begun to conduct chart reviews for these women. We will not be able to report the outcome based on chart reviews but have to rely on self-report instead. We will still complete chart reviews for all women who have given us permission and will compare chart review and self-reported outcomes to assess the accuracy of self-report data. Women in the intervention arm may be more likely to over report completion of follow-up than women in the control arm, due to social desirability bias. We will conduct sensitivity analyses based on our findings.

Task 5: Data Management and Analysis

Components a -d have been addressed in our previous reports. All tasks are completed, except data entry, which is ongoing.

e. Set up data entry program and enter information from chart reviews

This task has been started.

f. Data management and cleaning

Data management and cleaning is ongoing. Additionally, all written data and information storage devices are kept secure in locked filing cabinet. We are also using log-in and password protected computers in order to ensure confidentiality of study subjects.

g. Data analysis, preparation of annual reports and manuscripts.

At this time, we have conducted preliminary data analyses to prepare the annual reports required by the DOD and for a recent presentation (see attached).

KEY RESEARCH ACCOMPLISHMENTS:

Preliminary analyses of the follow-up surveys suggest that our intervention is effective in increasing adherence to follow-up of breast abnormalities in low-income Korean American who are screened through BCEDP. Complete follow-up is reported by 68% of the women in the control group and 93% of the women in the intervention group. This difference is statistically significant (Fisher's exact test, $p<.0007$). We will have to assess if chart reviews confirm these self-report findings.

REPORTABLE OUTCOMES:

In addition to an early presentation that introduced the study in 2005 and a 2007 presentation, we provided preliminary results at the 2008 DOD Era of Hope Conference.

Maxwell AE, Jo A, Bastani R. Increasing adherence to follow-up of breast abnormalities in low-income Korean American women. Era of Hope Department of Defense Breast Cancer Research Program meeting, Philadelphia, Pennsylvania, June 8-11, 2005.

Jo AM, Maxwell AE, Thai L, Kim MJ, Bastani R. Assisting Korean American women with follow-up of breast abnormalities. 23rd Annual UCLA Multi-Campus Family Medicine Research Forum. Northridge Hospital Medical Center. May 8, 2007 (Best Poster Award).

Maxwell AE, Jo AM, Bastani R. Peer navigation improves adherence to follow-up diagnostics among Korean American women with suspected breast abnormalities. Abstract #P7-1. Era of Hope Meeting, Department of Defense Breast Cancer Research Program, Baltimore, Maryland, June 25-28, 2008.

CONCLUSION:

The peer navigator intervention is well accepted and appreciated by the women and the participating clinics. Completion rates of diagnostic follow-up procedures are higher than we had expected in this group of women who had already missed their first follow-up appointment. The majority of women in the control group report that they completed all follow-up procedures without assistance. However, completion rates are substantially

higher in the intervention group. These preliminary results suggest that a peer navigator intervention is efficacious in this population.

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Rojas M, Mandelblatt J, Cagney K, Kerner J, Freeman H. Barriers to follow-up of abnormal screening mammograms among low-income minority women. Cancer Control Center of Harlem. Ethnicity and Health 1:221-8, 1996.

APPENDICES:

1. Revised Statement of Work
2. Preliminary Results from the Follow-up Survey
3. Maxwell AE, Jo AM, Bastani R. Peer navigation improves adherence to follow-up diagnostics among Korean American women with suspected breast abnormalities. Abstract #P7-1. Era of Hope Meeting, Department of Defense Breast Cancer Research Program, Baltimore, Maryland, June 25-28, 2008.

Statement of Work (Revised)

Task 1: Setup and Formative Research (Months 01-06)

a. Develop discussion guides for semi-structured interviews (English and Korean, using standard translation procedures including back translations)
b. Identify women who received a referral for follow-up procedures in the past 12 months from BCEDP logs. Conduct telephone interviews (N=20) with these women (Angela Jo, Kim Young)
c. Identify 5 health care professionals through participating sites and conduct semi-structured interviews (Maxwell, Jo, Young)
d. Draft intervention components (strategies, scripts, materials) and assessment forms (intervention activity logs, needs assessment questions) - all materials in English and Korean language
e. Hire and train 3 mature, English-Korean bilingual Korean American peer counselors
f. Establish procedures to identify women who missed follow-up appointments on a daily basis
g. Pretest intervention in 6-10 KA women, revise and finalize
h. Establish randomization procedure

Task 2: Enroll subjects into randomized trial (Months 07-30)

a. Identify eligible subjects (N=253 during the 2 year recruitment), randomize into the study and administer verbal informed consent to intervention subjects (choice of English or Korean).

Task 3: Conduct Intervention (Months 07-33)

a. Conduct telephone needs assessment and counseling for each newly enrolled intervention subject (N=86). Contact each intervention subject at least once every other week until completion of diagnostic follow-up/treatment. Offer intervention components as appropriate.
b. Document all contacts, responses to needs assessment questions, intervention requests and activities.
c. Conduct alternative protocol for intervention subjects who cannot be reached by telephone.
d. After completion of the follow-up survey, provide intervention to women in the control group who did not complete follow-up procedures.

Task 4: Data Collection (Months 3-40)

a. Collect and compile log sheets from contacts with intervention subjects (process measures) into a data base (months 7-35)
b. Develop (draft, translate, back translate, pretest, revise) follow-up survey based on the Adherence Model (months 3-12)
c. Hire and train interviewer(s) to conduct follow-up survey (months 12-13)
d. Conduct post-intervention survey with all subjects (N=160) 6 months after referral for diagnostic follow-up. Administer verbal consent prior to conducting survey to subjects in the control group (months 13-40)
e. Conduct chart reviews for all subjects (N=160) 6 months after referral for diagnostic follow-up (months 13-40)

Task 5: Data Management and Analysis (Months 1-42)

a. Transcribe and translate into English audiotapes from semi-structured interviews.
b. Analyze qualitative and quantitative data from Task 1.
   For qualitative data analysis, summarize transcripts from semi-structured interviews, including key points and notable quotes (in English and Korean language) using standard procedures (Krueger 1994); compare and consolidate summaries prepared independently by two Korean speaking investigators (Drs. Jo and Kim); sort findings by the domains of the Adherence Model.
   For quantitative analysis, tabulate findings from semi-structured interviews, including specific needs expressed, services requested and barriers and concerns voiced about follow-up procedures. Tabulate findings from chart reviews by adherence status.
c. Set up data entry programs and enter information from intervention log sheets, needs assessments, intervention requests and activities (process measures)
d. Set up data entry program and enter information from 6 month follow-up survey
e. Set up data entry program and enter information from chart reviews
f. Data management and cleaning will be ongoing
g. Data analysis, preparation of annual reports and manuscripts.

Deliverables

1st Annual Report

a. Summary of findings from semi-structured interviews and chart reviews
b. Intervention protocol, including questions for needs assessment, scripts for barrier counseling, fact sheets to answer frequently asked questions, and intervention strategies (English and Korean)
c. Training curriculum and materials for KA peer counselors (English and Korean)
d. Process measures: number of women enrolled; frequency with which intervention strategies are requested, offered, and implemented
e. Preliminary results of ongoing individual needs assessment

2nd Annual Report

f. Finalized chart review form and follow-up survey (English and Korean)
g. Updates on process measures and needs assessment

3rd Annual Report

h. Preliminary results of 6 month follow-up assessments (chart reviews, surveys)
i. Updates on process measures and needs assessment

Final Report

j. Final study protocol including all materials developed for training peer counselors and for delivering the individualized intervention (English and Korean)
k. Final report on process and outcome measures
l. Summary of findings for distribution to BCEDP sites (English and Korean)

Preliminary Results from the Follow-Up Survey 07-28-08

Table 1: Demographic characteristics and acculturation

Demographics	**total sample N=112**		**control group N=57**		**intervention group N=55**		**p-value (Fisher's Exact Test)**
	xbar	**s.d.**	**xbar**	**s.d.**	**xbar**	**s.d.**	
Age (N's included here just for you to see)	52.99 (N=98)	7.789	53.47 (N=45)	7.591	52.58 (N=53)	8.00	
Length of stay in U.S. (years)	16.68 (N=102)	9.41	16.98 (N=48)	9.122	16.42 (N=54)	9.74	
	N	**%**	**N**	**%**	**N**	**%**	
Born in Korea	101	99%	48	100%	53	98%	
Born in China	1	1%	0	0%	1	2%	.343
Marital Status							
never married	2	2%	1	2%	1	2%	
married	75	75%	36	74%	39	77%	
divorced	14	14%	9	18%	5	10%	
widowed	8	8%	3	6%	5	10%	
refuse	1	1%	0	0%	1	2%	.605
Annual household income							
< $10,000	23	24%	11	23%	12	24%	
$10,000 to < $20,000	26	27%	15	32%	11	22%	
$20,000 to < $30,000	18	19%	6	13%	12	24%	
$30,000 to < $50,000	14	14%	8	17%	6	12%	
> $50,000	8	8%	4	9%	4	8%	
don't know	1	1%	0	0%	1	2%	
refuse	0	0%	0	0%	0	0%	.677
Level of education							
less than 8th grade	9	9%	6	13%	3	6%	
8th to 11th grade	6	6%	2	4%	4	8%	
high school graduate	35	36%	20	42%	15	30%	
post high school, trade, tech school	1	1%	0	0%	1	2%	
1 - 3 years college	13	13%	6	13%	7	14%	
college graduate	31	32%	13	27%	18	36%	
some graduate work or degree	1	1%	1	2%	0	0%	
refuse	2	2%	0	0%	2	4%	.406
Acculturation							
Language used with friends							
Korean and English	7	7%	3	6%	4	8%	
Mostly Korean	39	40%	21	45%	18	36%	
Only Korean	50	52%	23	49%	27	54%	
Mostly Korean/Chinese	1	1%	0	0%	1	2%	.659
Reading language							
Only English	1	1%	1	2%	0	0%	
Half Korean, half English	7	7%	3	6%	4	8%	
Mostly Korean	25	26%	10	21%	15	30%	
Only Korean	65	66%	34	71%	31	62%	.524
Television language							
Mostly English	6	6%	3	6%	3	6%	

Half Korean, half English	18	18%	8	17%	10	20%	
Mostly Korean	34	35%	18	38%	16	32%	
Only Korean	40	41%	19	40%	21	42%	.940
Do you consider yourself …							
More Korean	82	84%	40	83%	42	84%	
More American	3	3%	2	4%	1	2%	
Equal blend	12	12%	6	13%	6	12%	
Chinese	1	1%	0	0%	1	2%	.719

Table 2: General health and health insurance status

	total sample		**control group**		**intervention group**		**p-value (Fisher's Exact Test)**
General Health	**N**	**%**	**N**	**%**	**N**	**%**	
How would you rate your overall health?							
Excellent	3	3%	3	6%	0	0%	
Very good	6	6%	3	6%	3	6%	
Good	24	24%	15	31%	9	18%	
Fair	43	43%	19	39%	24	48%	
Poor	23	23%	9	18%	14	28%	.188
Has doctor ever told you that you have …							
Heart problems	10	10%	3	6%	7	14%	.250
Stroke	0	0%	0	0%	0	0%	-
Hypertension	18	18%	5	10%	13	26%	.042
Diabetes	4	4%	2	4%	2	4%	.610
Cancer	6	6%	1	2%	5	10%	.097
Other	36	36%	13	27%	23	46%	.044
Family History of Cancer	41	44%	21	46%	20	42%	.697
How comfortable discussing your health care with physician							
very	29	30%	11	22%	18	37%	
somewhat	58	59%	30	61%	28	57%	
not	6	6%	5	10%	1	2%	
don't know	4	4%	2	4%	2	4%	
refuse	1	1%	1	2%	0	0%	.268
How worried were you about your future health?							
very	15	15%	6	13%	9	18%	
quite	28	29%	13	27%	15	30%	
a little	45	46%	24	50%	21	42%	
not	10	10%	5	10%	5	10%	.825
Health Insurance							
Has health Insurance	18	18%	8	16%	18	20%	.636
Type of health insurance†							
Private	6	32%	0	0%	6	60%	
HMO	6	32%	5	56%	1	10%	
Medi-Cal	2	11%	2	22%	0	0%	
Other	5	26%	2	22%	3	30%	.024

Table 3: Self-reported adherence to diagnostic follow-up procedures

	total sample		control group		intervention group		p-value (Fisher's Exact Test)
	N	%	N	%	N	%	
Adherent to follow-up exams	92	82%	39	68%	53	96%	
Not-adherent to follow up exams	20	18%	18	32%	2	4%	
Test Results							
Fibroadenoma	2	2%	0	0%	2	4%	.238
Microcalcifications	4	5%	2	6%	2	4%	.691
Need further test	12	14%	4	12%	8	16%	.586
Cancer	4	5%	1	3%	3	6%	.518
Normal	61	55	25	44	36	66	.093

Table 4: Knowledge and attitudes regarding diagnostic follow-up procedures

	total sample		control group		intervention group		p-value (Fisher's Exact Test)
Know the exam	N	%	N	%	N	%	
yes	81	83%	37	77%	44	88%	
no	17	17%	11	23%	6	12%	.216
Understanding of why doctor/nurse recommended exam							
very well	54	54%	22	45%	32	63%	
pretty well	37	37%	21	43%	16	31%	
not well	9	9%	6	12%	3	6%	.211
How important is it to get a follow up exam?							
very	83	82%	40	80%	43	84%	
somewhat	15	15%	9	18%	6	12%	
not	2	2%	1	2%	1	2%	
don't know	1	1%	0	0%	1	2%	.637
How supportive would your family/friends be?							
very	53	54%	25	50%	28	57%	
somewhat	38	38%	21	42%	17	17%	
not	7	7%	4	8%	3	3%	
don't know	1	1%	0	0%	1	1%	.632
Need help on decision to get or not get exam							
Can make the decision alone	74	74%	38	76%	36	72%	
Don’t know	1	1%	0	0%	1	2%	.579
With regards to getting my exam, I want to do what my friends think I should do.							
agree	18	18%	8	16%	10	20%	
disagree	80	82%	41	84%	39	80%	.602
Getting the follow up exam gives peace of mind							
strongly agree	31	36%	13	27%	18	31%	
Agree	63	64%	34	69%	29	58%	
Disagree	4	4%	1	2%	3	6%	
strongly disagree	1	1%	1	2%	0	0%	.363
Worried that exam would show cancer							
very	26	26%	11	22%	15	30%	
somewhat	56	57%	28	57%	28	56%	
not	17	17%	10	20%	7	14%	.567

Nervous about getting breast cancer							
very	24	25%	12	25%	12	25%	
somewhat	50	51%	23	47%	27	55%	
not	24	25%	14	29%	10	20%	.611
Worry/nervousness affected decision to get exam							
encouraged to get exam	79	81%	40	82%	39	80%	
avoided the exam	2	2%	2	4%	0	0%	
did not affect	16	16%	7	14%	9	18%	
refuse	1	1%	0	0%	1	2%	.353

Table 5: Aspects rated as very important for quality of life by Korean-American women

Aspect	Total N	N	%
Being healthy	96	83	87
Satisfactory family relationships	95	64	67
Live without stress	95	53	56
Leading a religious life	95	46	48
Successful family members	95	40	42
Absence of financial difficulties	95	37	39
Living honorably	95	30	32
Good social networks/relationships	95	28	30
Success in work	95	22	23
Engaging in activities you like	95	21	22

Table 6: Barriers to follow-up exams (strongly agree) for breast abnormalities among Korean-American women

Barriers	Total N	N	%
lack of time	96	26	27
concerned about cost	96	31	32
believe exam is not necessary without symptoms	98	31	32
worried to find cancer	99	23	23
language barriers	99	13	13
exam is difficult to schedule	96	11	12
embarrassment	96	8	8
forget appointment	96	6	6
long waiting times in facility	97	5	5
lack of social support	96	4	4
exam is inconvenient to take	97	3	3
exam is painful	97	3	3

Peer Navigation improves Adherence to Follow-up Diagnostics among Korean American women with suspected Breast Abnormalities

Annette E. Maxwell, Angela M. Jo, Roshan Bastani
University of California, Los Angeles, School of Public Health and Division of Cancer Prevention and Control Research

Background and Objectives: Incomplete follow-up of potential breast abnormalities may contribute to disparities in breast cancer survival, especially in low-income, non-white populations. The purpose of this study is to test an intervention in the form of peer navigation to assist Korean American women who have been identified with a potential breast abnormality through the Breast Cancer Early Detection Program (BCEDP) and who have missed their first follow-up appointment (at-risk women). To recruit study participants, we have partnered with two community clinics in Koreatown that provide free breast cancer screening to low income uninsured women through the Cancer Detection Program.

Methodology: We are testing our intervention in a randomized controlled trial, where half of the women are randomized to the control arm and half to the intervention arm. All subjects in the control arm are receiving usual care follow-up through the BCEDP case manager. They are recruited 6 months after their missed appointment to complete a telephone survey. Subjects in the intervention arm are recruited prospectively immediately after their missed appointment and receive peer navigation in addition to usual care. They complete the telephone survey at 6 month follow-up. Assessment includes adherence to follow-up procedures and related knowledge, attitudes and quality of life. Chart reviews are being conducted to validate self-reported adherence to follow-up procedures. We are also collecting extensive process measures in the intervention arm including number and type of intervention activities requested and delivered in order to estimate the feasibility of institutionalizing the peer navigation program.

Results to date: Since August 2005, we have identified 192 women who are eligible to participate in our study. Of them, 99 (51%) have been assigned to the control arm and 94 (49%) have been assigned to the intervention arm. Of those in the intervention arm, 76 (81%) have agreed to participate and have received various types of assistance from the peer navigator including: rescheduling of appointments (50%), reminder calls (81%), directions to the hospital (30%), translating (57%), filling out forms (55%), answering questions regarding the follow-up process (94%), and emotional support (72%). Among women who have completed the telephone survey 6 months after their missed appointment, 76% in the control group (44/58) and 95% in the intervention group (52/55) have reported completion of all recommended follow-up procedures ($p=.007$).

Conclusions: About 75% of women in the control group reported that they completed all follow-up procedures without assistance. However, completion rates were substantially higher in the intervention group. These preliminary results suggest that a peer navigator intervention is efficacious in this population. If chart reviews confirm our preliminary findings in the total sample, this intervention may assist in decreasing breast cancer disparities among Korean American women.